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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/540,305	**Applicant(s)** KEREK, FRANZ	
	Examiner SAMUEL W. LIU	**Art Unit** 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 33-47* is/are pending in the application.

4a) Of the above claim(s) *4-6,8,9,33-38 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-9 and 33-47 are pending.

The amendment filed 8/27/08 which amends claims 1-9, 33-39 and 43-47 has been entered. Claims 10-32 has been canceled by the amendment filed 3/24/08. Claims 4-6, 8-9, 33-38 and 43-47 remain withdrawn from further consideration by the examiner. Claims 1-3, 7 and 39-42 are examined in this Office action.

Withdrawal of the objection and rejections

- The objection to the specification is withdrawn in light of the amendment of the specification thereof.

- The rejection under 35 USC 101 of claims 1-3 and 7 is withdrawn in light of the amendment of the claims thereof.

- The rejection under 35 USC 112, second paragraph of claims 1-3, 7 and 39-42 is withdrawn in light of the amendment of claims 1-2 and 7. However, there is a new ground 112/2 rejection (see below).

- The rejection under 35 USC 112, first paragraph (written description) of claim 7 is withdrawn in light of the amendment of claim 7.

New-Objection to Specification

The disclosure is objected to because of the following informalities:

At page 50, last paragraph, line 1 of the substituted specification filed 8/27/08, "the peptide Hellethionin B (BZT)" is not apparent to which sub-type of "Hellethionin B", e.g., Hellethionin B1, 2, 3, 4, 5, or 6, it refers.

New-Claim Rejections - 35 USC §102

* This new ground of rejection is based on CLAIM INTERPRETAION of claim 1 language "...peptide <u>of</u> the structure..." which is considered be open-ended.

> The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 39 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated Curtis et al. (US Pat. No. 7125687 B1).

Curtis et al. teach a "pen-1B" polypeptide of SEQ ID NO:25 (see column 5, line 67, and columns 61-66) which amino acid residues 28-73:

"CG**CC**TTCATTG**C**CTT**C**GGGCCTGCG**C**TCG**C**C**C**TTTA**T**GT**C**TTCACC" reads on the instant claim 1 peptide formula

"**CC**XXXXXXX**C**XXX**C**XXXXXXXXXX**C**XXX**C**X**C**XXXXX**T**XX**C**XXXXXX" (instant SEQ

ID NO:13). In view of the open-ended language of claim 1, Curtis et al. teach the peptide of claim 1.

*The above "pen-1B" sequence of residue 28-73 does not meet the structural limitation of claim 2; and thus, claim 2 is not included in the rejection.

Curtis et al. teach a composition comprising the "pen-1B", i.e., the pen polypeptide which is used for diagnosis or therapy (col.4, lines 40-58); i.e., said composition is a pharmaceutical composition, which anticipates claim 39.

Curtis et al. teach that the composition contains the "pen polypeptide" (wherein "pen" refers to "presenilin enhancer protein", see col. 4, line 4) and presenilin which is a cytotoxic active agent (see "*Discussion of art*" [4] set forth in the Office action mailed 5/29/08), which anticipates claim 41.

New-Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope enablement

Claims 1-2, 7 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, because while the specification appears to enable the isolated cysteine–containing peptide set forth in claim 3 such as hellethionin-A, does not reasonably provide enablement for the peptides having generic peptide formula of SEQ ID NO:12, 13 or/and 14 set forth in claim 1 and the pharmaceutical composition comparing the peptides thereof (claims 39-42). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2)The nature of the invention:

The instant invention is directed to the isolated bioactive cysteine-containing peptides. While the specification teaches effect of peptide "HT-C" (i.e., hellethionin-C of SEQ ID NO:8) on human breast cancer cells (Example 4), effect of the peptides “hellethionin C” (“CZT”), “hellethionin D (i.e., “DZT”, SEQ ID NO: 9) and “hellethionin B (i.e., “BZT”) and mixture thereof on cancer cell line COLO-205 (see Example 7, the substituted specification filed 8/27/08); and, effect of peptide “HT-A” (i.e., SEQ ID NO: 1) on cytokine production of primary human immune cells (Example 3, the substituted specification filed 8/27/08), the specification fails to teach biological function of the generic peptide formula of SEQ ID NO:12, 13 or/and 14 set forth in claim 1. The specification does not teach any substitutions in “X” position in the formula of SEQ ID NO:12, 13 or 14 retain the biological functions of the “hellethionin A, B, C, or D” discussed above. In this case, the scope of the claims is outside the bounds of the enablement provided by the specification and prior art and would have resulted in the necessity of undue experimentation.

(3) The unpredictability of the art:

Comeglio et al. teach that protein functionality of substitutions of non-cysteine amino acid residues in a protein (cysteine rich) is unpredictable (see page 45th paragraph, Comeglio et al. (2004) *Human Mutation*, (published online without Vol. and page numbers cited, pages 1-6). This suggests that the unpredictability of the art is high.

(4) The state of the prior art:

The general knowledge and level of skilled in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Because the art does not teach or provide guidance as to construct mutants or variants which has the formula of instant SEQ ID NO:12, 13 or 14 and therapeutic use the mutants or variants thereof, e.g., treating breast cancer (see above). The relative art (e.g., Comeglio et al.) teach unpredictability of functionality of the cysteine rich proteins resulted from mutagenesis. The specification needs to provide sufficient guidance to be considered enabling for the claimed peptides and the pharmaceutical composition comprising the peptides thereof (claims 39-42).

(5) The quantity of experimentation necessary:

In the absence of working examples with regard to the genus stated above, unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, and in absence of teaching regarding core or consensus motifs or sequences (except conserved cysteine residues), it would take undue trials and errors to practice the claimed invention. The quantity of experimentation is large and not routine. One skilled in the art would have been required to carry out an undue experimentation for screening for and characterizing various polysaccharides with the structural feature discussed above for their capability of treating diverse autoimmune disease mentioned above.

(6) The relative skill of those in the art:

The general knowledge and level of skill in the art do not supplement the omitted description with respect to a massive number of variant sequences of polypeptide and broad scope of disorders encompassed by the claims. In view of the preceding factors (1-5), the level of skill in this art is high and requires at least a molecular biologist with several years of experience in peptide chemistry, pharmacology/immunology as well as knowledge in oncology and medicine. Yet, even with a level of skill in the art as those mentioned in precedence, predictability of the results is still highly variable.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

New-Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andresen et al. (*Plant Mol. Biol.* (1992) 19, 193-204).

Andresen et al. teach a cysteine rich polypeptide "KSCCKNTTGRNCYNACRFAGGSRPVCATACGCKIISGPTCPRDYPK" (see page 200, Fig. 7B, the peptide sequences, residues 28 to74). This peptide is an obvious variation of instant peptide formula of claim 1 "XXCCXXXXXXXCXXXCXXXXXXXXXCXXXCXC XXXXTXXCXXXXXX".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the cysteine rich polypeptide above which is obvious variant of instant polypeptide of SEQ ID NO:12. This is because claim 1 discloses SEQ ID NO:12 and SEQ ID NO:13 which have the same length, and the same "cysteine pattern" with difference only in residue 23 and residue 37 of SEQ ID NO:12 is "Q" and "X", respectively, while residue 23 and residue 37 of SEQ ID NO:13 is "X" and "T", respectively, suggesting that residue 37 is variable without influence bioactivity of the polypeptide. Provided that the SEQ ID NOs: 12 and 13 represents a polypeptide with two different versions, then, "G" (underlined residue 37) in SEQ ID NO:12 and "T" (underlined residue 37) in SEQ ID NO:13 are obvious structural variation each other. Therefore, the reference teaching per se render the claimed polypeptide (claim 1) *prima facie* obvious.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Samuel W Liu, Ph.D./
Examiner, Art Unit 1656
November 19, 2008

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657/6